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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,871	01/29/2007	Patrick Lewis Blott	SMNPH.005APC	6837

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EXAMINER

HAWTHORNE, OPHELIA ALTHEA

ART UNIT	PAPER NUMBER
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3772

NOTIFICATION DATE	DELIVERY MODE
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12/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/575,871	Applicant(s) BLOTT ET AL.	
	Examiner OPHELIA HAWTHORNE	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 0325129.5.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04-17-2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed on 04/17/2006.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.

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(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

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- (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR

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1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 1 - 5 recites the recitation “a cleansing means for selectively removing materials” and “optionally bleed means for bleed”, it is unclear if the applicant has sufficiently invoked 35 U.S.C., 6th paragraph.

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Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner what is the "relevant fluid" as recited in the claims. Is the relevant fluid apart of the cleansing fluid or the irrigant?

Claims 4 & 5 recites the limitation "relevant fluid" in claims. There is insufficient antecedent basis for this limitation in the claim.

Claims 1 - 3 & 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "optionally" renders the claims indefinite because it is unclear whether the limitation (s) following the word are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the phrase "is not an integer" which renders the claim vague and indefinite.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1 – 10** are rejected under 35 U.S.C. 102(e) as being anticipated by **Risk, Jr. et al. (US 6,755,807 B2)**.

Regarding claim 1, Risk, Jr. et al. discloses an apparatus for cleansing wounds (**Figs. 1, 9**), comprising a conformable wound dressing (**14, Figs. 1, 9**) having a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound (**[Col. 10], lines 19 – 21**) and characterized in that it also comprising a cleansing means or bandage member (**604, Fig. 9**) & (**[Col. 10], lines 25 – 31**) for selectively removing materials that are deleterious to wound healing from wound exudates (**[Col. 10], lines 38 – 43**), which means is under the backing layer and sits in the underlying wound (**300, Fig. 9**) in use and a moving device or pump (**110**) & (**[Col. 10], lines 44 – 45**) for moving fluid within the cleansing means, and optionally bleed means or check valve (**400, Fig. 6**) for bleeding the cleansing means. It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only

requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Regarding claim 2, Rick, Jr. et al. discloses an apparatus for cleansing the wound is a single-phase system in which the fluid that is moved through the means for fluid cleansing or bandage member **(604, Fig. 9)** is wound exudates optionally mixed with an irrigant **([Col. 6], lines 2 – 4)** which passes into, through and out of the cleansing means back to the wound bed **([Col. 10], lines 46 – 59)**.

Regarding claim 3, Rick, Jr. et al. discloses an apparatus for cleansing wounds is a multiple-phase system in which the means for fluid cleansing comprising a chamber or bandage member **(604, Fig. 9)** containing a cleansing fluid **([Col. 10], lines 52 – 55)** separated from the wound exudates by means of a permeable integer or gauze **(618, Fig. 9)** and the cleansing fluid and/or the wound exudates optionally mixed with irrigant **([Col. 4], lines 2 – 4)** is/are moved through the means for fluid cleansing by the device for moving fluid or pump **(110) & ([Col. 10], lines 44 – 45)**.

Regarding claim 4, Risk, Jr. et al. discloses an apparatus **(as shown in Figs. 1, 9)** for cleansing wound is operated as a circulating system, in which the relevant fluid **([Col. 4], lines 2 – 4)** passes through the cleansing means one or more times in only one direction via check valve (or one way valve) **(400)** and tube **(18, Figs. 1, 9)**.

Regarding claim 5, Risk, Jr. et al. discloses the cleansing wound is operated as a reversing system, in which the relevant fluid passes through the cleansing means at least once in opposing directions. The claim limitation “operated as a reversing system” is being treated as a functional recitation. While features of an apparatus may be recited

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either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does. The device of Risk, Jr. et al. is capable of being operated as a reversing system. (Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim.

Regarding claim 6, Risk, Jr. et al. discloses an apparatus for cleansing wounds is characterized in that the moving fluid from the syringe **(24, Fig. 9)** is only the cleansing fluid.

Regarding claim 7, Risk, Jr. et al. discloses the moving fluids via syringe **(24, Figs. 1, 9)** are the cleansing fluid and the wound exudates optionally mixed with irrigant.

Regarding claim 8, Risk, Jr. et al. discloses the wound cleansing apparatus is characterized in that the permeable integer is selectively permeable to materials deleterious to wound healing in the wound exudates. The claim limitation “the permeable integer is selectively permeable to materials deleterious to wound healing in the wound exudates” is being treated as a functional recitation. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does. The gauze of Risk, Jr. et al. is capable of functioning as a selectively permeable integer. . (Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir.

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1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim.

Regarding claim 9, Risk, Jr. et al. discloses an apparatus for wound cleansing characterized in that the permeable integer or gauze **(618)** is not an integer selectively permeable to materials deleterious to wound healing and that in the cleansing fluid, or in one or more solid integers with at least one surface in contact with the cleansing fluid, in the means for fluid cleansing, there are one or more materials that can remove materials deleterious to wound healing in the wound exudates. The claim limitation “one or more materials that can remove materials deleterious to wound healing in the wound exudates” is being treated as a functional recitation. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does. The gauze which is being treated as a membrane/or integer of Risk, Jr. et al. is capable of removing one or more than one materials that can remove materials deleterious to wound healing. (Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim.

Regarding claim 10, Risk, Jr. et al. discloses a method of treating wounds to promote wound healing using the apparatus for cleansing wounds **(as shown in Figs. 1, 9)**.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OPHELIA HAWTHORNE whose telephone number is (571)270-3860. The examiner can normally be reached on Monday - Friday, 7:30 AM - 5:00 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ophelia Hawthorne/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772

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